OCT 5 - 2005

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:

August 22, 2005

Submitter's Information: 21 CFR 807.92(a)(1)

Mr. Didier Lemoine, Technical Director
ETIAM s.a.
20 Rue Professeur Jean Pecker
3500, Rennes
France
Fax: 33-299-43380

Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	ETIAM STAR PACS Components™
Common Name:	Picture Archiving Communications System
Device Classification:	892.2050 System, Image Processing
Product Code:	LLZ

Predicate Device: 21 CFR 807. 92(a)(3)

510(k) Number	K042313
Regulation Number	892.2050
Device Name	INTEGRADWEB MPR/MIP
Applicant	DYNAMIC IMAGING INC.
Classification Product Code	LLZ
Device Classification Name	SYSTEM, IMAGE PROCESSING, RADIOLOGICAL

Device Description: 21 CFR 807 92(a)(4)

ETIAM STAR PACS Components™ are software applications that make possible the capturing, storage, distribution, and networking of medical images at distributed locations. In cases where DICOM images are not directly available to ETIAM STAR PACS Components™, the system can acquire medical images using a DICOM gateway, which generates DICOM-type files. For example, film digitizers obtain images from old film and convert them to meet DICOM standards and stored in an archive. Stored files are transmitted using a network and can be viewed or manipulated from an imaging workstation.

Indications for Use: 21 CFR 807 92(a)(5)

ETIAM STAR PACS Components™ is a device that receives medical images (including mammograms) and data from various imaging sources. Images and data can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations.

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Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA. Typical users of this system are trained professionals, e.g. physicians, radiologists, nurses, medical technicians, and assistants.

Technological Characteristics: 21 CFR 807 92(a)(6)

ETIAM STAR PACS Components™ is a software product that handles digital medical images.

The device does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification for ETIAM STAR PACS Components™ contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device.

ETIAM STAR PACS Components™ has been and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey. The submission contains the results of a hazard analysis and the "Level of Concern for potential hazards has been classified as "Minor".

OCT 5 - 2005

ETIAM s.a.
℅ Mr. Carl Alletto
1600 Manchester Way
CORINTH TX 76210

Re: K052358
Trade/Device Name: ETIAM STAR
PACS Components™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and
communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 7, 2005
Received: August 31, 2005

Dear Mr. Alletto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
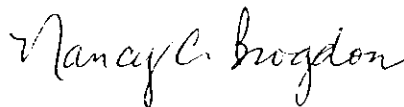
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon
Director, Division of Reproductive,
  Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

(Indications for Use Form)

510(k) Number: Ko52358

Device Name:
ETIAM STAR PACS Components™

Indications for Use:

ETIAM STAR PACS Components™ is a device that receives medical images (including mammograms) and data from various imaging sources. Images and data can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations.
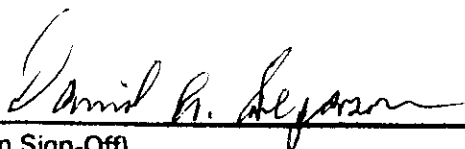
Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

Typical users of this system are trained professionals, e.g. physicians, radiologists, nurses, medical technicians, and assistants.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __✗__   AND/OR   Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)   (21 CFR 807 Subpart C)

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(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number _____KD52358_____